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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/808,031    03/03/97    INOUYE    S    377.5888P

HM12/0224

GERARD J WEISER  
WEISER AND ASSOCIATES  
SUITE 500  
230 SOUTH FIFTEENTH STREET  
PHILADELPHIA PA 19102

EXAMINER

SRIVASTAVA, D

ART UNIT

PAPER NUMBER

1652

27

DATE MAILED: 02/24/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

Art Unit: 1652

### DETAILED ACTION

#### *Claim Rejections - 35 USC § 112*

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 are improper for the reference to sequences in "Figure 14". Claims reciting sequences should refer to SEQ ID #'s only. It is suggested that the claims recite "Figure 14, which sequences are shown in SEQ ID NO's: 30-36", or some similar recitation.

NOTE: Claim 15 is improper for the recitation of "YXDD", as this does not refer to a specific SEQ ID NO.

#### *Claim Rejections - 35 USC § 103*

NOTE: The elected subject matter of an RT from *Escherichia (coli)* has been found free of the prior art (along with that from *Myxococcus xanthus*), and thus the prior art search has expanded to include the remaining claimed subject matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-~~16~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Inouye et al. (US PAT. 5,320,958 or US PAT. 5,434,070), in view of the combination of Rice et al. (July, 1993), Xiong et al. (1990), and Hsu et al. (Apr. 1992).

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NOTE: The instant application is a continuation of 08/269,118, filed June 30, 1994. This application is a CIP of applications which are only enabled for RT's and msDNA from *E. coli* and *M. xanthus*. The earlier applications do not contemplate nor enable in any way the breadth encompassed by the instant claims and the teachings of the instant specification (and that of 08/269,118) regarding RT's from other bacterial species. The instant application receives the benefit filing date only of June 30, 1994, for subject matter of RT's from any organism other than *E. coli* and *M. xanthus*. Thus, the Inouye et al. Patents are considered available prior art against this subject matter.

The Inouye et al. patents teach the isolation and production of reverse transcriptases from *Escherichia coli* and *Myxococcus xanthus*. Methods of production and isolation/purification are described and stated to be established in the art. These patents do not teach RT's from other bacterial or prokaryotic species.

Rice et al. teach of the diversity of retron elements, which encode reverse transcriptases (RT's), in numerous bacterial groups. The RT-encoding retrons were assayed and detected in species of *Proteus*, *Klebsiella*, *Salmonella*, *Nannocystis*, *Rhizobium*, and *Bradyrhizobium*, and states that the retron of *Stigmatella aurantiaca* was known (page 4250). The "retron elements were discovered by detecting the presence of msDNA by the RT extension method". Particular strains were identified that possessed the retron elements, msDNA and RT's.

Xiong et al. disclose a phylogenetic tree of 82 different retron elements encoding RTs from plants, animals, protozoans, viruses and bacteria. Also provided are amino acid sequences for numerous RT's from these organisms.

Hsu et al. teach of the "similarity between *Myxococcus xanthus* and *Stigmatella aurantiaca* reverse transcriptase genes associated with" msDNA. Also provided is the amino acid sequence of the RT.

Thus, given the teachings of the Inouye et al. patents regarding the production of reverse transcriptases once detected, in light of the teachings of the secondary references concerning the knowledge of RT-encoding retrons in a wide range of prokaryotic sources, including viral and bacterial, it would have been obvious to one of ordinary skill in the art to have isolated and

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purified the existing RT's from any of the sources described and known to contain such enzymes. The Inouye et al. patents are, of course, enabling for the isolation/purification of the described *Escherichia coli* and *Myxococcus xanthus*, and the secondary references provide direct motivation and a high expectation of success in producing the existing RT from any of species of *Proteus*, *Klebsiella*, *Salmonella*, *Nannocystis*, *Rhizobium*, *Bradyrhizobium* and *Stigmatella (aurantiaca)*. The references not only describe which specific organisms and genres of organisms contain the RT's, but detail screening methods for the further detection of such in other species. Thus, the production of the claimed RT's from these other specifically-described sources would have been obvious to one of ordinary skill in the art, given the specific knowledge of the RT's in specific organisms, in combination with the direct motivation and guidance provided by the references to obtain the RT's using techniques which were described and well within the ordinary level of skill in the art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 5,320,958, and claims 1-7 of US Patent 5,434,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a bacterial RT (elected) from Escherichia. The patented claims are both directed to a bacterial RT from Escherichia coli. Thus, the subject matter of the claims overlaps and would have been obvious to produce from the teachings of the patents.

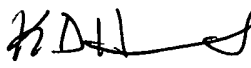
**NOTE:** While applicants have filed Terminal Disclaimers to this rejection in the parent application, these do not transfer and apply to the instant application. Submission of new Terminal Disclaimers is required to overcome the instant rejection.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith D. Hendricks, in Art Unit 1652, whose telephone number is (703)308-2959.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The fax phone number for this Tech. Center is (703) 308-4242. Unofficial papers and proposed amendments may be faxed directly to (703)308-0294.

  
KEITH D. HENDRICKS  
PRIMARY EXAMINER  
GROUP 1800

kdh  
June 3, 1998